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Jan Faergemann

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NEW YORK, NY 10019

EXAMINER

RAMACHANDRAN, UMAMAHESWARI

ART UNIT

PAPER NUMBER

1627

NOTIFICATION DATE

DELIVERY MODE

04/22/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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maierp@dicksteinshapiro.com

Office Action Summary	Application No. 10/562,608	Applicant(s) FAERGEMANN ET AL.	
	Examiner UMAMAHESWARI RAMACHANDRAN	Art Unit 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,8-14 and 18-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,8-14 and 18-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 1/13/2010 amending claims 1 and 18. Claims 3, 5-17 have been cancelled. Claims 5-7 have been withdrawn from consideration. Claims 1, 2, 4, 8-14 and 18-25 are examined based on the merits.

Response to Remarks

Applicants' arguments regarding the rejections have been fully considered and found not to be persuasive. Applicants' arguments are addressed below. Applicants' amendments, further search and consideration necessitated the modified and new rejections given below. Accordingly, the action is made Non-Final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1, 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 7, 8, 10, 11, 20, 22, 23, 24, 26 of copending Application No. 11/791,577.

Claims 1 and 18 of the instant application is drawn to a method of inhibiting the growth of bacteria comprising administering pentane-1, 5-diol or a method of disinfecting a non-porous surface contaminated with multiple resistant bacteria comprising administering a disinfecting composition comprising 15% or more by weight of pentane 1,5 diol.

Claims 1, 2, 4, 7, 8, 10, 11, 20, 22, 23, 24, 26 of copending Application No. 11/791,577 are drawn to a pharmaceutical composition comprising 15, 16, 17, 18, 19 or 20 % weight of the diols including 1, 2 pentane diol and use of such composition as antimicrobial composition.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the co-pending application teach the use of a pharmaceutical composition comprising 1, 2 pentane diol in treating microbial infections.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 7-14, 18-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining minimum inhibitory concentration for different strains of s.aureus, Staph, MRSA, enterococcus, E.coli, Enterobacter and resistance indicated against selected antibiotics (methicillin resistant, fucidic acid resistant, coagulation-negative Staph, vancomycin resistant enterococci etc but does not reasonably provide enablement for inhibiting the growth of all multiple resistant bacteria by administration of "multiple resistant bacteria bacteriostatic agent" as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and, (8) the quantity of experimentation necessary.

(1, 5) The nature of the invention and the Breadth of the Claims:

The instant claims are drawn to a method of inhibiting the growth of multiple resistant bacteria comprising administering 15% by weight or more of pentane 1,5 diol as multiple resistant bacteriostatic agent. The claims are very broad with respect to the

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multiple resistant bacteria inhibited by multiple resistant bacteriostatic agent, pentane 1,5 diol.

(2)/(3) *The state of the art /The predictability of the art:*

The article 'Antibiotic Resistance' (http://en.wikipedia.org/wiki/Antibiotic_resistance) teaches the following resistant pathogens: (1) Vancomycin resistant *Staphylococcus aureus* (2) CA-MRSA (community acquired MRSA) now emerged as emerged as an epidemic that is responsible for rapidly progressive, fatal diseases including necrotizing pneumonia, severe sepsis and necrotizing fasciitis and is resistant (3) MRSA (methicillin Resistant *S.aureus*) (4) *Streptococcus pneumoniae* resistant to penicillin and other beta-lactams (5) *E.coli* resistant to five fluoroquinolone variants (6) *Mycobacterium tuberculosis* is commonly resistant to isoniazid and rifampin (7) Besides intrinsic resistance, *P. aeruginosa* easily develop acquired resistance either by mutation in chromosomally-encoded genes, or by the horizontal gene transfer of antibiotic resistance determinants (8) Clindamycin-resistant *C. difficile* (9) *Acinetobacter baumannii* with multidrug resistance (MRAB)..(10) Other pathogens showing some resistance include *Salmonella*, *Campylobacter*, and *Streptococci*. Todar (Todar's Online Textbook of Bacteriology, Chapter, Bacterial Resistance to Antibiotics, p 1-4) teaches the various multiple drug resistant organisms as MRSA - methicillin/oxacillin-resistant, *Staphylococcus aureus*, VRE - vancomycin-resistant enterococci, ESBLs - extended-spectrum beta-lactamases (which are resistant to cephalosporins and monolactams), PRSP - penicillin-resistant *Streptococcus pneumoniae* (p 2 of the chapter). Moinuddin (<http://www.apic.org/AM/AMTemplate.cfm?Section=Brochures&Template=/CM/Content>

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Display.cfm&ContentFileID=2573, 2005) teaches MDR-TB (multiple drug resistant mycobacterium tuberculosis) and PPNG (penicillinase producing *Neisseria gonorrhoeae*) and MRSA and VRE (Vancomycin resistant Enterococci) as examples of drug resistant bacteria. Also, there are several causes of antimicrobial drug resistance. They include mutation (natural biological cause), gene transfer, inappropriate use of antibiotics, hospital use etc. Despite the advanced studies in antibiotic resistance of bacteria it is still not predictable from the art or from the specification that 1, 5 pentane diol can inhibit the growth of all multiple resistant bacteria known so far and yet to be discovered. Applicants have shown inhibitory effect of pentane 1, 5 diol on different types of bacteria, including multiple-resistant bacteria but only for MR resistant against fucidin, methicillin, vancomycin (only for enterococcus), ciprofloxacin and timetoprim for the bacterial strains tested. For example, recently Huff (Naturalnews.com, Mar 6 2010) reported that a new drug resistant bug, *Acinetobacter* (superbug) is plaguing many hospitals. Also, Baker (Naturalnews.com, July 18 2009) reported about CA-MRSA type of drug resistant bug causing pneumonia. Applicants have claimed that pentane, 1, 5 diol is multiple resistant bacteriostatic agent, an agent that will inhibit the growth of existing multiple drug resistant strains as well the ones to be discovered. However, it is not predictable that this agent will be effective in inhibiting all drug resistant bacteria known and yet to be discovered from the results provided by the Applicant as there are different types of bacteria that are resistant to drugs not tested by the Applicants.

(4) The relative skill of those in the art:

The relative skill of those in the pharmaceutical development and medical treatment arts is high, requiring advanced education and training.

(6, 7) The amount of guidance given and the presence of working examples:

It has been established that, “The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art.” *In re Fisher*, 427 F.2d 833, 839 166 USPQ 18, 24 (CCPA 1970). The specification provides guidance to determining minimum inhibitory concentration (MIC) for different strains of s.aureus, Staph, MRSA, enterococcus, E.coli, Enterobacter and resistance indicated against selected antibiotics (methicillin resistant, fucidic acid resistant, coagulation-negative Staph, vancomycin resistant enterococci etc for the drugs fucidin, methicillin, vancomycin (only for enterococcus), ciprofloxacin and timetoprim (see p 6-8 of the specification)

(8) The quantity of experimentation necessary:

Given that the instant claims encompass administration of 15% of pentane 1,5 diol as multiple resistant bacteria bacteriostatic agent, the guidance of the specification is towards determining the MIC and growth inhibition for multiple resistant bacteria where the drugs are fucidin, methicillin, vancomycin (only for enterococcus), ciprofloxacin and timetoprim. One having ordinary skill in the art have to conduct experiments to find out whether pentane 1,5 diol is multiple resistant bacterial bacteriostatic agent for different multiple drug resistant bacteria and for their various strains for the drugs that they are resistant to. First a person of ordinary skill in the art

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have to conduct experiments (for yet to be discovered, multiple resistant bacteria) or research from prior art to find out the type of drug(s) the bacterial strain is resistant to and then conduct experiments with 1, 5 pentane diol to find out at whether the compound inhibits the growth of that particular strain and its minimum inhibitory concentration. There is no guidance provided in the specification to conduct experiments to test the drug(s) to which bacterial strain they are resistant to. In order to practice the above claimed invention, one of ordinary skill in the art would have to first determine the drug(s) that are proven to be resistant to and predict which different bacterial strains would be resistant to the different drugs and the concentration of 1, 5 pentane diol for inhibiting the growth of such multiple resistant bacteria. Therefore, it would require undue, unpredictable experimentation to find whether pentane 1,5 diol is a multiple-resistant bacteriostatic agent, that is an agent that inhibits the growth of all multiple resistant bacteria that is known and yet to be discovered. *Genetech*, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 8-10, 18, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck et al. (U.S. 5,369,129).

Swanbeck et al. teaches a preparation for topical treatment of infections caused by virus, fungi, bacteria comprising 1, 5 pentane diol. The reference teaches a composition comprising 50% of 1, 5 pentane diol and 50% ethanol solution (see abstract, col1, lines 56-57). Also, the reference has data showing a study of pentane-1,5 diol against certain bacteria such as *S.aureus*, *S.epidermidis*, *C.albicans*, *T.rubrum*, *P.avale* (Table 1). The reference teaches a method of treating an infection caused by a virus by topical administration of a composition comprising 1,5-pentane diol.

The reference does not explicitly teach the topical administration of the composition in patients with bacterial infections.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have topical administered a composition comprising 15% by weight or more of pentane 1,5 diol and a pharmaceutical carrier in a method of treating patients with bacterial infections because the patent title is "Preparation of topical treatment of infections caused by bacteria" and the patent teaches administration of such

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composition to patients with herpes virus. The reference teaches the preparation of the composition claimed and administration of the same to the patients with viral infections. Also, the reference teaches that formulation is effective against bacteria such as *S.aureus*, *S.epidermidis*, *C.albicans*, *T.rubrum*, *P.avale* (Table 1). One having ordinary skill in the art would have been motivated to administer the composition claimed to patients with bacterial infections topically in expectation of success as well to achieve the therapeutic benefits attained in such administration. The reference shows data in study 2 of the activity of pentane 1, 5 diol against various bacteria and an in vitro study of using pentane 1, 5 diol to study its activity against virus. Though the reference does not explicitly teach addition of an antimicrobial composition comprising pentane 1, 5 diol to non-porous surface in a method of disinfecting however it is obvious to one having ordinary skill in the art that addition of such composition to glass surfaces indicates a method of disinfecting the glass surface or non porous surface as pentane 1, 5 diol is taught as an antibacterial agent by Swanbeck. The reference does not explicitly teach rinsing the surface with water or an aqueous detergent composition after treating the surface with 1, 5 pentane diol. It would have been obvious to one having ordinary skill in the art at the time of the invention to have rinsed surfaces at least with water that has been treated with disinfectants or antimicrobial such as 1, 5 pentane diol in order to clean and remove the antimicrobial composition from the surface.

Claims 1, 8, 10-13, 20, 22, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (U.S. 6,348,203) and further in view of Tsao et al. (U.S. 5,411,597).

Goodman et al. teaches a method of preparing a viscous hydrogel composition, for use in a topical treatment of a skin condition including a pharmaceutically active agent, a polysaccharide, gelling or a thickening agent (col.2 , lines 12-13) (e.g. hydroxy alkyl cellulose), a water-miscible organic solvent and water, wherein the pharmaceutically active agent is an antimicrobially active nitroimidazole drug (0.75% in example 1), the water-miscible organic solvent is a water-miscible alkylene glycol that includes pentylene glycol (synonym of 1,5 pentylene glycol or 1, 5 pentane diol) (see abstract, col. 5-6, claim 1, claims 22, 17, 18, 19). Also, the reference teaches that the composition is useful in treating conditions involving infection responsive to an antimicrobially active nitroimidazole drug.

The reference teaches up to 5% of alkylene glycol in example 1 but does not explicitly teach the composition comprises 15% by weight of more of pentane 1-5 diol

Tsao et al. teaches a disinfection solution comprising C2-C6 alkanol, C3-C8 alkylene glycol, a pharmaceutically acceptable surfactant, optionally a buffer and water (see Abstract). The reference further teaches that the alkylene glycol is selected from 1,2-propylene glycol, 1,2-butylene glycol, 1,5-pentylene glycol etc and the amount range from 10-50% by weight (col. 3, lines 13-19, lines 20-25). The reference also teaches addition of a surfactants and viscosity enhancers such as hydroxy methyl cellulose (col. 7, lines 40-50) to the composition.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Goodman's composition to add more 1, 5 pentane diol to formulate a composition comprising 15% by weight of more of pentane 1-5 diol because

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of the teachings of Tsao et al. Tsao et al. teaches disinfectant solution primarily for use in contact lenses comprising alkylene glycols such as pentylene glycol in an amount ranging from 10-50% by weight. One having ordinary skill in the art would have been motivated to add such an amount of pentane 1, 5 diol to Goodman's composition in expectation of success in preparing such formulations and using the same in treating infections.

Claim 13, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (U.S. 6,348,203) and further in view of Tsao et al. (5,411,597) as applied to claims 1, 8, 10-13, 20, 22, 23, 24 above and further in view of Noll et al. (U.S. 5,370,876).

Goodman et al. and Tsao et al. teachings discussed as above. Tsao teaches addition of surfactants to the composition comprising alkylene glycols. The reference does not teach explicitly the addition of a detergent in the composition.

Noll et al. teaches a protective skin cream composition comprising 15-40 wt % of an alkali metal fatty acid salt, an effective amount of an antimicrobial compound, 5-20% of a polyol effective as an emollient (See abstract). The reference further teaches that the water soluble salts of fatty acids are used to provide water repellency.

It would have been obvious to one having ordinary skill in the art to have added detergents such as salts of a fatty acid in the antimicrobial composition of Goodman et al. because of the teachings of Noll. Noll teaches antimicrobial compositions comprising antimicrobial agents, alkali metal fatty acid salt, polyols etc for use as protective creams for healthcare workers. Polyols include pentylene glycol according to the prior art

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teachings of Tsuzuki et al. (see claim 5, U.S. 6,121,327). One having ordinary skill in the art would have been motivated in adding such salts in an antimicrobial composition comprising an antimicrobial agent and a polyol in expectation of success in preparing such formulations and using the same for therapeutic purposes and also to provide water repellency.

Claims 4, 14, 19, 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck et al. (U.S. 5,369, 29) as applied to claims 1, 2, 8-10, 18, 22 and in view of Buseman et al. (U.S. 2002/0192273).

Swanbeck et al. teachings discussed as above.

The reference does not teach the carrier comprises a patch of a woven or non-woven material or combination thereof.

Buseman et al. teaches adhesive patches for treating or preventing bacterial infections for topical applications in a mammal (see p 22-23, claims 100-103).

It would have been obvious to one having ordinary skill in the art to impregnate or add antibacterial compositions comprising a pharmaceutical carrier in patches because of the prior art teachings. The prior art Buseman et al. teaches adhesive patches in treating bacterial infections in mammals by topical application. Accordingly, one having ordinary skill in the art at the time of the invention would have been motivated to make patches comprising 1, 5 pentane diol and use it in a method of inhibiting the growth of multiple-resistant bacteria because Swanbeck teaches the antimicrobial properties of the compound and Buseman teaches that antimicrobial compositions can be provided via adhesive patches in treating bacterial infections in mammals.

Response to Arguments

(1) ODP rejection:

Applicants' argue that the claims of the co-pending application are directed to the possible use of a combination of at least three different diols to inactivate micro-organisms but fail to teach or suggest any of those micro-organisms are multiple-resistant bacteria and the instant application is clearly not obvious over the co-pending application. In response, the co-pending application claims a method of treating a microbial infection (claim 26) comprising administering a composition comprising diols including 1,5 pentane diol. The claim is very broad in scope and it includes infection by all kinds of bacteria including multiple resistance. There is no limitation in the claim that excludes the multidrug resistance bacteria type. Similarly, claim 23 of the co-pending application includes use of diols comprising pentane 1,5 diol in treating infection caused by all types of microorganism including resistant type and do not exclude multi resistant bacteria. Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention that pentane,1 ,5, diol is useful in treating bacterial infections including multi resistant bacteria from the claims of the co-pending application.

(2) 103(a) rejection:

Applicants' argue that the claims of the instant application is towards a method of inhibiting the growth of multiple resistant bacteria comprising topical administration of pentane1,5 diol and just because a given antibiotic may be active against a bacteria which is not multiple-resistant does not provide any reasonable basis for believing it will be effective against a strain of the same bacteria which has become multiple-resistant.

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This is not persuasive because studies have shown that clindamycin is useful in treating *S.aureus* infections as well MRSA infections (see Table 1, Table 2) (Bamberger, *Am Fam Physician*, 72, 12, 2005). It would have been obvious to one having ordinary skill in the art to have tried using pentane 1,5 diol in treating multiple resistance bacteria because it is known in the art (Swanbeck, Tsao as above) that the compound is useful in treating infections caused by *S.aureus*, *S.epidermidis*, *C.albicans*, *T.rubrum*, *P.avale* bacteria and also known for its safety. It would have been obvious to one having ordinary skill in the art to try using pentane 1,5 diol in treating multiple resistance bacteria for cost-effective reasons and availability. A person of ordinary skill in the art would have been motivated to using pentane 1,5 diol in treating multiple resistance bacteria in expectation of reasonable amount of success.

Applicants' argue that pentylene glycol is the INCI name for 1,3-pentanediol and thus Goodman is thus deficient in that it fails to teach or suggest that alkylene glycols have any antibiotic activity, multiple-resistant or otherwise, and also fails to teach or suggest 1,5-pentanediol. In response, one of the chemical names for 1,5 pentane diol is pentylene glycol according to CAS registry. Goodman teaches compositions comprising alkylene glycol including pentylene glycol and hence using the composition comprising the same compound will have the same property even Goodman has not stated that pentylene glycol has antibiotic activity as it is well known from the prior art (Swanbeck) that 1,5 pentane diol has shown the effect against various types of bacteria. Any properties exhibited by or benefits provided the composition are inherent and a chemical composition and its properties are inseparable. Tsao et al. teaches a

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disinfection solution comprising C2-C6 alkanol, C3-C8 alkylene glycol which includes 1,5 pentane diol that is effective against a wide range of ocular pathogens. As stated above, it would have been obvious to one having ordinary skill in the art to have tried using pentane 1,5 diol in treating multiple resistance bacteria because it is known in the art (Swanbeck, Tsao as above) that the compound is useful in treating infections and hence known for its safety in patients. It would have been obvious to one having ordinary skill in the art to try using pentane 1,5 diol in treating multiple resistance bacteria for cost-effective reasons and availability. A person of ordinary skill in the art would have been motivated to using pentane 1,5 diol in treating multiple resistance bacteria in expectation of reasonable amount of success.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to UMAMAHESWARI RAMACHANDRAN whose telephone number is (571)272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1627
